DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 23, 2014

4Web, Incorporated
% Rich Jansen, Pharm.D.
Silver Pine Consulting, LLC
11821 Bramble Cove Drive
Fort Myers, Florida 33905

Re: K142112
Trade/Device Name: 4Web Spinal Implant Products
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: August 21, 2014
Received: August 25, 2014

Dear Dr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142112

Device Name
4Web Spinal Implant Products

Indications for Use *(Describe)*
The ALIF STS Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation and must be used with autograft bone. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

The 4-Web Cervical Spinal Truss System (STS) is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. 4-Web Cervical STS implants are used as an adjunct to fusion in the cervical spine and are placed via an anterior approach at the C-3 to C-7 disc levels using autograft bone. Patients should have received 6 weeks of non-operative treatment prior to treatment with the devices. The device should be used with supplemental fixation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary
K142112

Date Prepared: September 22, 2014

Submitter Jessee Hunt, President
4Web, Inc.
6170 Research Rd. Suite 219
Frisco, TX 75033
Phone: (800) 285-7090
Fax: 972-488-1816

Device: 4Web Spinal Implant Products
Product Class: Class II
Classification: 21 CFR §888.3080 Intervertebral Body Fusion Device
Common Name: Interbody Fusion Device
Product Codes: MAX, ODP
Panel Code: 87

Purpose: The purpose of this submission is to gain clearance of previously cleared devices as sterile, packaged products.

Predicate Device(s):
The 4Web Spinal Implant Products is substantially equivalent to the previously cleared 4Web Spinal Implant Products, ALIF STS (K112316) and the Cervical STS (K121741). Each device is the primary predicate device for the respective proposed change.

Device Description:
The ALIF STS Interbody Fusion Device is a titanium implant that is designed to provide mechanical support to the lumbar spine while biologic fusion takes place. The device is an "open architecture" design consisting of trusses mathematically designed to provide maximum support with the greatest amount of open space throughout the implant for bone growth and fusion. The implant is made from Ti6Al4V alloy.

The device is available in three basic "footprint" sizes, small, medium and large. These sizes are available in 6 and 12 degree lordosis and each of these in 9 heights ranging from 8mm to 16mm in 1mm increments.

The Cervical STS Interbody Fusion Device is a titanium implant that is designed to provide mechanical support to the lumbar spine while biologic fusion takes place. The device is an "open architecture" design consisting of trusses mathematically designed to provide maximum support with the greatest amount of open space throughout the implant for bone growth and fusion. The implant is made from Ti6Al4V alloy.

The device is available in two basic "footprint" sizes, 17mm x 14mm and 14mm x 11mm. These sizes are available in zero and 7 degree lordosis and each of these in 8 heights ranging from 5mm to 12mm in 1mm increments.

Indications for Use:

The ALIF STS Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation and must be used with autograft bone. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

The 4-Web Cervical Spinal Truss System (STS) is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. 4-Web Cervical STS implants are used as an adjunct to fusion in the cervical spine and are placed via an anterior approach at the C-3 to C-7 disc levels using autograft bone. Patients should have received 6 weeks of non-operative treatment prior to treatment with the devices. The device should be used with supplemental fixation.

Intended Use:
The ALIF STS and Cervical STS have the same intended use as the predicate devices of the same name. The only change is that the product is being offered pre-packaged and sterile.

Performance Standards:
Performance testing includes:

- Gamma sterilization per ANSI/AAMI/ISO 11137-2
- Packaging per ISO 11607-1
- Package integrity tests per ASTM F88-09, ASTM F1886-09 and ASTM F1929-12
- Shipping performance per ASTM D4169-09
- Shelf life tests per ASTM F1980-07

Conclusion:
4Web, Inc concludes that these Spinal Implant Products are substantially equivalent to the previously cleared 4Web Spinal Implant Products. The packaging and sterilization processes have been properly validated and raise no new questions of safety or effectiveness.